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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,530	03/17/2004	Jonathan Bingham	370878005US1	3519

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PERKINS COIE LLP  
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EXAMINER
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RIGGS II, LARRY D

ART UNIT	PAPER NUMBER
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1631

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01/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/802,530		BINGHAM ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Larry D. Riggs II		1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendments filed 09 October 2007 are acknowledged and entered.

#### ***Status of Claims***

Cancellation of claims 1-14 are acknowledged. New claims 15-21 are pending and examined on the merits.

#### ***Specification***

The abstract of the disclosure is objected to because the recited phrase "It may varies the color saturation" in line 4 is unclear. The examiner suggests that the word "varies" be changed to "vary", for grammatical correctness. Correction is required. See MPEP § 608.01(b).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, throughout the claim, claim 16 in line 1; claim 18, in line 1, and claim 19 in line 1, recite the limitation "modules and exons". The metes and bounds of the limitation are unclear. The specification provides that a module is a subsequence of a gene product, (see specification, paragraph 37), and that some embodiments of the

invention may contain both intronic and exonic modules, (see specification, paragraph 38 and Figures 1-5). In most examples provided by applicant, modules represent an intron or an exon, (see Figures 1-5). One skilled in the art would be unclear as to distinguish modules and exons of said limitation, when examples in the specification have modules representing introns, exons and extension of exons and introns.

Claim 15 recites the limitation "a scaled length  $L_s$ ' of each subsequence for graphical representation" in lines 8-9. and likewise the limitation "displaying a graphical representation wherein the modules or exons of the splice variants are aligned with corresponding modules or exons of other splice variants of the gene and wherein the representation indicates the relative expression levels of the modules and exons" in lines 13-15. The metes and bounds of the limitations are unclear. One skilled in the art would not know how the result of the first recited limitation " $L_s$ ' " is corresponds with the graphical representation in the second recited limitation.

Claim 15 recites the limitation "having a length  $L_s$ " in line 7. The metes and bounds of the limitation are unclear. One skilled in the art would not know if the module, exon or splice variant has a length  $L_s$ . If the applicant is referring to only the module and exon, then one skilled in the art would be unclear if the module and exon are of the same length.

Claim 15 recites the limitation "expression level data for exon-exon junction indicator polynucleotides" in lines 11-12. The metes and bounds of the limitation are unclear. One skilled in the art would not know if the data is for said polynucleotides or if the data is from the use of said polynucleotides.

Claim 15 recites the limitation "the representation indicates the relative expression levels of the modules and exons" In lines 15-16. The metes and bounds of the limitation are unclear. One skilled in the art would not know if the expression levels are from modules and exons from the splice variants, recited in lines 13-14 or if the expression levels are from modules and exons from the other splice variants, recited in line 14.

Claim 16 recites the limitation "the exon" in line 1. There is no clear antecedent basis for the limitation. It is unclear which exon the limitation refers because a plurality of exons are recited in the independent claim 15.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-21 are rejected under 35 U.S.C. 102(e) as being anticipated by  
Loraine et al. (US 2004/0049354).

The instant invention provides a method of displaying a graphical representation of expression levels of a plurality of splice variants of a gene in one or more samples,

each of the plurality of splice variants of the gene having modules and exons comprising,

identifying the modules and exons for each splice variant of the gene, each representing a subsequence of the splice variant and having a length  $L_s$ ;

applying a mathematical function to the length  $L_s$  of each subsequence to obtain a scaled length  $L_s'$ ;

determining a relative expression level for each module or exon by applying a mathematical algorithm to expression level data for exon-exon junction indicator polynucleotides; and

displaying a graphical representation wherein the modules or exons of the splice variants are aligned with corresponding modules or exons of other splice variants of the gene, wherein the representation indicates the relative expression levels of the modules and exons.

Regarding claim 15, Loraine et al. shows modules and exons, (e.g. Figure 3 of applicant's disclosure) of splice variants with various lengths, (see paragraph 139; Figure 12); scaling the length of the modules and exons of splice variants with a variety of scales that may vary in units and magnitude including linear, logarithmic and other types of scales, (see paragraph 137); applying a hybridization data to a model-fitting algorithm, wherein data may be obtained from exon-exon junction probes, (see paragraphs 89 and 113); and displaying a graphical representation of modules and exons of splice variants, wherein the representation indicates relative expression levels of the modules and exons (see paragraphs 5, 140, 141 and 144; Figure 12).

Regarding claim 16, Loraine et al. shows non-overlapping exons and modules (see paragraph 144; Figure 12, 1210).

Regarding claim 17, the specification in paragraph 38, provides that the invention may display trimmed or extended exon in one module, while the remainder of the exon is another module. This is interpreted to mean that a partial exon may be displayed. Loraine et al. shows displaying modules of exons, introns or partial exons, (see paragraph 144).

Regarding claim 18, Loraine et al. shows exons and modules are constitutive, (See Figure 12, top two splice variants of 1210).

Regarding claim 19, Loraine et al. shows exons and modules are non-constitutive, (See Figure 12, comparing top two splice variants of 1210 with third splice variant of 1210, also referred in the figure 12 as 1211, selected splice variant).

Regarding claims 20 and 21, Loraine et al. shows scaling the length of the modules and exons of splice variants with a variety of scales that may vary in units and magnitude including linear, logarithmic and other types of scales, (see paragraph 137). This is interpreted to mean that to change scales by linear units or logarithmically, means to apply a linear or logarithmic function to the measured units of the current scale, respectively, (see paragraphs 137-138; Figure 12).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the cancellation of claims 1-14.

No other arguments were set forth against this rejection than those already responded to above.

### ***Conclusion***

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry D. Riggs II whose telephone number is 571-270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/  
Larry D. Riggs II  
Examiner, Art Unit 1631

/ Shubo (Joe) Zhou/  
Shubo (Joe) Zhou, Ph.D.  
Primary Examiner